

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2270601	(X3) Date Survey Completed 07/29/2025
Name of Provider or Supplier Summit Pediatric Clinic - Providence	Street Address, City, State 1200 Providence Park Suite 100, Birmingham, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Hematology Sysmex XP-300 maintenance records, a review of the Sysmex XP-300 Instructions For Use, and an interview with the Laboratory Manager (LM) and Testing Personnel (TP), the laboratory failed to document quarterly maintenance from the date of the last survey, 08-29-2023 through the date of the current survey, 07-29-2025. The findings include: 1. A review of the Sysmex XP-300 Maintenance Hematology log maintenance records revealed no documentation of quarterly (every 3 months) maintenance for 23 months, from 08-29-2023 through 07-29-2025. 2. A review of the Sysmex XP-300 Instructions For Use, section 12, page 12-12, under "Clean SRV", revealed the following instructions, "When the main power switch is turned ON, and if either the counter value exceeds 4,500, or if 3 months have passed since the last maintenance, a message will appear prompting the operator to perform periodic maintenance (SRV cleaning)...". 3. During the exit conference on 07-29-2025 at 2:46 PM, the LM and TP confirmed the above findings.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental</p>

conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on a review of the 2023 Sysmex XP-300 analyzer Quality Control (QC) records and an interview with the Laboratory Manager (LM) and Testing Personnel (TP), the laboratory failed to document the monitoring of shifts and trends of test performance over time. The surveyor noted no documentation of Levey-Jennings (L-J) charts or peer group data for four of the four months reviewed in 2023. The findings include: 1. A review of the Sysmex XP-300 QC records revealed no evidence of L-J charts or peer group data available for review from September through December 2023. 2. The LM and TP confirmed the above findings during the exit conference on 07-29-2025 at 2:46 PM.